

REMARKS

By the above actions, claims 1-13 have been amended to correct the noted and discovered informalities. In view of these actions and the following remarks, reconsideration of this application is requested.

In response to the 35 USC § 112, second paragraph, rejections of claims 1-13, these claims have been amended to address the noted informalities and based on the Examiner's most helpful suggestions. Accordingly, all of the pending claims are now in compliance with 35 USC § 112, so that withdrawal of this rejection is requested.

The rejection of claims 1-13 based on Shusterman (U.S. Patent Application Publication 2002/0143263) is inappropriate, at least insofar as it relates to the pending claims, because Shusterman fails to disclose, teach or suggest all of the features recited in the pending claims. Specifically, in order to assert that independent claims 1, 11 and 13, are anticipate by Shusterman, the Examiner presents various arguments based on different paragraphs from Shusterman. However, upon reading of the Shusterman patent application as a whole, the following novel differences between Shusterman's disclosure and the inventions of independent claims 1, 11 and 13 can be seen.

For example, Shusterman is specifically described by the present applicant in the paragraph beginning on line 13 of page 2 of the present application, and from the second paragraph of page 3 it can be seen how the present invention is designed to improve upon the teachings of Shusterman. Specifically, Shusterman discloses, for example, in the noted paragraph of page 2 the structuring of analysis is achieved by constructing at least two, and preferable three, information scales that represent the most significant parameters at different levels of detail.

The first scale, low-resolution Scale I, represents a small number of primary elements such as the intervals between the heart beats, duration of electrocardiographic PQ, QRS, and QT-intervals, amplitudes of P-, Q-, R-, S-, and T-waves. The second scale, intermediate-resolution Scale II, enables serial changes in each of the said elements can be determined using a mathematical decomposition into series of basic functions and their coefficients. High-resolution Scale III, enables combined serial changes in all primary elements to be determined to provide complete information about the dynamics of the signal. These scales

require successively higher processing power. These characteristic described by the present applicant are described in greater detail in the description of paragraphs [0016], [0017], [0018] and [0019] of Shusterman and which clearly indicates that Shusterman is more complex than the present invention because the invention of independent claims 1, 11 and 13 does not employ different resolution scales, as with Shusterman for the analysis thereof. Furthermore, the invention of independent claims 1, 11 and 13 includes the novel feature of analyzing the QT curvature of an ECG. Moreover, paragraph [0018] of Shusterman discloses employing Principal Component Analysis (PCA), which advantageously need not be employed with invention of independent claims 1, 11 and 13.

Paragraph [0054] of Shusterman discloses that a processing unit 41 is programmed to detect a plurality of characteristic points, such as the onset, peak and offset of P-, Q-, R-, S-, T-, U-waves, and then computes characteristic parameters or primary elements, which include wave amplitudes, and ST-segment, duration of PQ-, QRS-, and QT intervals. This differs from the invention of independent claims 1, 11 and 13, because by the groups of parameters used by Shusterman are only examples of duration parameters, wherein there is no disclosure in Shusterman of symmetry, flatness or complexity parameters and much less of single parameters recited in the dependent claims. The only parameter that could be arguably disclosed by Shusterman is a QT-interval. However, in claim 6, the corresponding parameter is defined as QTc, which is the QT-interval normalized by the square root of the RR interval according to the Bazett's formula, and not merely a QT-interval. Accordingly, Shusterman is silent with respect to the above-noted and other claimed parameters.

Paragraph [0055] of Shusterman states that a comparative unit 44 compares newly acquired waveforms and newly computed primary elements with waveforms and primary elements previously stored in a storage unit 43. Paragraph [0055] further states that an output unit 60 includes a screen or a set of indicators for displaying ECG waveforms and the computed primary elements, compared with the previously stored primary elements, or compared with the default reference values. However, comparing curvature in this manner is a rather bad way of analyzing such curves. Specifically, a newly obtained curve can indicate diseases that cannot be seen by comparing such curves, wherein a deviation, for example, in symmetry can be so small that such a deviation cannot be determined by merely comparing

curves on a screen, as with Shusterman. Therefore, such a template matching scheme, as disclosed by Shusterman, is a rather primitive way of analyzing ECG curvature. By contrast, the invention of independent claims 1, 11 and 13 need not employ a comparison of curves, as with Shusterman, but rather analyzes curvature by combining different parameters.

Paragraph [0037] of Shusterman states that a further object of his invention is to provide an ECG analyzing system that includes a monitoring device for receiving and analyzing ECG signals and which includes means for communication with an external computer to which the ECG signals can be forwarded for more complex analysis. By contrast, the invention of independent claims 1, 11 and 13 need not employ a monitoring device and communication with external computers.

Paragraph [0054] of Shusterman further describes QRSSTU-waves and computer characteristics parameters or primary elements, which include amplitudes of the waves, and ST-segment duration of PQ, QRS and QT-intervals. By contrast, the invention of independent claims 1, 11 and 13 employ quite a different set of parameters, which are not disclosed, taught or suggested by Shusterman.

Paragraph [0067] of Shusterman is only a repetition of the parameters which were described in the paragraph [0054]. As previously noted, only an example of a duration parameter is arguable disclosed by Shusterman.

As previously noted, paragraph [0054] of the Shusterman discloses principal components analysis (PCA), which advantageously need not be employed with the invention of independent claims 1, 11 and 13.

As previously noted, paragraph [0055] of Shusterman describes comparative units 44, wherein an output unit 60 may alternatively or additionally feed output data to an action unit 80 for sounding an alarm, generating a vibration, or taking appropriate measures, such as applying drugs or adjusting a therapy mode. Figure 14 of Shusterman is a simple two-dimensional coordinate system showing the duration of a QT-interval in relation to a T-wave amplitude. However, figure 14 only shows the combination of two parameters. Applicant submits that there is a novel difference between merely applying drugs, as described in paragraph [0055] of Shusterman, and analyzing QT-curvature of an ECG for indicating drug induced changes, as is possible with the invention of independent claims 1, 11 and 13.

Accordingly, the invention of independent claims 1, 11 and 13 is patentably distinguishable over Shusterman. Dependent claims 2-10, and 12 are allowable on their own merits, and for at least the reasons set forth above with respect to their independent claims 1 and 11.

Therefore, in the absence of new and more relevant prior art being discovered, this application should now be in condition for allowance and action to that effect is requested. However, while it is believed that this application should now be in condition for allowance, in the event that any issues should remain, or any new issues arise, after consideration of this response which could be addressed through discussions with the undersigned, then the Examiner is requested to contact the undersigned by telephone for the purpose of resolving any such issue and thereby facilitating prompt approval of this application.

Respectfully submitted,

/Carlos R. Villamar, Reg. # 43,224/  
Carlos R. Villamar  
Reg. No. 43,224

Customer No. 25570

Roberts Mlotkowski Safran & Cole, P.C  
PO Box 10064  
McLean, VA 22102

Direct Telephone: 703-584-3273

CRV:DSS:kmm